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101ST CONGRESS *2d Session* | SENATE | REPORT 101-530

TRANSPLANT AMENDMENTS OF 1990

OCTOBER 12 (legislative day OCTOBER 2), 1990.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2946]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2946) to amend the Public Health Service Act to revise and extend the program establishing the National Bone Marrow Donor Registry, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute, and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transplant Amendments Act of 1990".

SEC. 2. TABLE OF CONTENTS.

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—NATIONAL BONE MARROW DONOR REGISTRY

Sec. 101. Establishment of a National Bone Marrow Donor Registry.
Sec. 102. Savings provisions.

S543-33

TITLE II—ORGAN TRANSPLANTS

Sec. 201. Assistance for organ procurement organizations.
Sec. 202. Organ procurement and transplantation network.
Sec. 203. Policy standards and guidelines.
Sec. 204. General provisions respecting grants and contracts.
Sec. 205. Administration.
Sec. 206. Report.
Sec. 207. Study by general accounting office.
Sec. 208. Effective date.

TITLE III—IMMUNOSUPPRESSIVE DRUG THERAPY

Sec. 301. Block grants.

TITLE I—NATIONAL BONE MARROW DONOR REGISTRY

SEC. 101. ESTABLISHMENT OF A NATIONAL BONE MARROW DONOR REGISTRY.

(a) REGISTRY.—Title III of the Public Health Service Act (42 U.S.C. 301 et seq.) is amended—

(1) by redesignating parts I, J, and K as parts J, K, and L, respectively; and

(2) by inserting after section 377 (as added by section 207 of this Act) the following new part:

"PART I—NATIONAL BONE MARROW DONOR REGISTRY

"SEC. 379. NATIONAL REGISTRY.

"(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the 'Registry') that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors that shall include representatives of donor centers, transplant centers, persons with expertise in the social science, and the general public.

"(b) FUNCTIONS.—The Registry shall—

"(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

"(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

"(3) ensure that the pool of potential donors that form the Registry is ethnically diverse so that an individual in a minority group has a comparable chance of finding a suitable unrelated donor as an individual not in a minority group;

"(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

"(5) recruit potential bone marrow donors;

"(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and

"(7) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

"(c) CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual donor centers, donor registries, marrow collection centers, and marrow transplant centers—

"(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

"(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

"(3) procedures to ensure the proper collection and transportation of the marrow;

"(4) standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning—

"(A) the resources available through the Registry;

"(B) all marrow donor registries meeting the standards described in this paragraph; and

"(C) in the case of the Registry—

"(i) the comparative costs of all charges incurred by patients prior to transplantation; and

"(ii) the success rates of individual marrow transplant centers; and

"(5) standards that—

"(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing donor center for marrow donors and potential marrow donors; and

"(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure.

"(d) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (c).

"(e) CONSULTATION.—The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

"(f) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

"(g) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

"(h) RECORDS.—

"(1) RECORDKEEPING.—Each recipient of a contract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

"(i) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (c)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (c)(5)(B), shall be fined not more than $50,000 or imprisoned not more than 2 years, or both.

"(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $17,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.

"SEC. 379A. STUDY BY THE GENERAL ACCOUNTING OFFICE.

"(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates—

"(1) the costs and benefits of the search process for an unrelated bone marrow donor among donor registries;

"(2) the extent to which donor registries protect donor confidentiality;

"(3) the relationship between the Registry established under this part and individual donor centers;

"(4) the effectiveness and appropriateness of policies and procedures of donor centers, transplant centers, and donor registries, including—

"(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

"(B) the maintenance and updating of donor files; and

"(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

"(5) the ability of the donor registries to adopt changes in medical understanding and practice; and

"(6) the costs associated with tissue typing.

"(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives

and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.".

(b) CONFORMING AMENDMENT.—Section 373 of the Act (42 U.S.C. 274a) is amended—

(1) in the section heading, by striking "and Bone Marrow Registry";

(2) by striking "(a)"; and

(3) by striking out subsection (b).

SEC. 102. SAVINGS PROVISIONS.

(a) IN GENERAL.—This title, and the amendments made by this title, shall not affect any legal document, including any order, regulation, grant, or contract, in effect on the date of enactment of this Act, or any administrative proceeding or lawsuit pending on the date, that relates to the bone marrow registry established under section 373(b) of the Public Health Service Act (as it existed before the amendment made by section 101(b) of this Act).

(b) CONTINUED EFFECT.—A legal document described in subsection (a) or an order issued in a lawsuit described in subsection (a) shall continue in effect until modified, terminated, or revoked.

(c) PROCEEDINGS.—In any administrative proceeding or lawsuit described in subsection (a), parties shall take appeals, and officials shall hold proceedings and render judgments, in the same manner and with the same effect as if this title had not been enacted.

TITLE II—ORGAN TRANSPLANTS

SEC. 201. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) SECTION HEADING.—Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended in the section heading by striking "assistance for".

(b) AUTHORITY REGARDING CERTAIN GRANTS.—

(1) SPECIAL PROJECTS.—Section 371(a)(3) of the Act (42 U.S.C. 273(a)(3)) is amended by striking "may make grants for special projects" and inserting the following: "may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects".

(2) CONSIDERATIONS IN MAKING CERTAIN GRANTS.—Section 371(a) of the Act (42 U.S.C. 273(a)) is amended by striking paragraph (4).

(c) SERVICE AREA OF QUALIFIED ORGAN PROCUREMENT ORGANIZATIONS.—

(1) IN GENERAL.—Subparagraph (E) of section 371(b)(1) of the Act (42 U.S.C. 273(b)(1)(E)) is amended to read as follows:

"(E) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire standard metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,".

(2) CONFORMING AMENDMENT.—Section 402(c)(3) of the Health Omnibus Programs Extension of 1988 (Public Law 100-607; 42 U.S.C. 273 note) is repealed.

(d) EFFECTIVENESS REGARDING NUMBER OF ORGANS PROCURED.—Section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following new paragraph:

"(2) Not later than 180 days after the date of the enactment of this paragraph, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).".

(e) TECHNICAL CORRECTION REGARDING PUBLIC LAW 100-607.—Section 402(c)(2) of the Health Omnibus Programs Extension of 1988 (Public Law 100-607; 102 Stat. 3115) is amended by inserting "at the end" after "the comma".

(f) AUTHORIZATION OF APPROPRIATIONS.—Section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)) is amended by striking "1988 through 1990" and inserting "1991 through 1995".

SEC. 202. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) MINIMUM QUALIFICATIONS OF CONTRACTOR.—Section 372(b)(1) of the Public Health Service Act (42 U.S.C. 274(b)(1)) is amended—

(1) in subparagraph (A), by striking "which is not engaged in any activity unrelated to organ procurement" and inserting "that has an expertise in organ procurement and transplantation"; and

(2) in subparagraph (B), to read as follows:

"(B) have a board of directors—

"(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

"(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.".

(b) RESPONSIBILITIES OF NETWORK.—Section 372(b)(2) of the Act (42 U.S.C. 274(b)(2)) is amended—

(1) in subparagraph (D)—

(A) by inserting "nationwide" after "organizations in the"; and

(B) by inserting "equitably among transplant patients" after "organs";

(2) by striking "and" at the end of subparagraph (I);

(3) by striking the period at the end of subparagraph (J) and inserting ", and"; and

(4) by adding at the end the following new subparagraph:

"(K) work actively to increase the supply of donated organs.".

(c) TECHNICAL CORRECTION.—Section 372(b)(2)(F) of the Act (42 U.S.C. 274(b)(2)(F)) is amended by striking "compatability" and inserting "compatibility".

(d) EFFECTIVE DATE.—The amendments made by subsection (a) shall become effective on December 31, 1990.

SEC. 203. GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS.

Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in subsection (a), by striking "No grant" and all that follows through "373" the first place that the term appears and inserting the following: "No grant may be made under this part";

(2) in subsection (b)—

(A) by striking paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively;

(B) by striking "section 371" in paragraph (1) (as so redesignated) and inserting "section 371(a)(1)";

(C) by striking "paragraphs (2) and (3) of section 371(a)" in the first sentence of paragraph (2) (as so redesignated), and inserting "section 371(a)(2)"; and

(D) by adding at the end the following new paragraph:

"(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years."; and

(3) in subsection (c)—

(A) by inserting "or contract" after "grant" in the first sentence of paragraph (1);

(B) by inserting "and contracts" after "grants" each place the term appears in the second sentence of paragraph (1); and

(C) by inserting "or contract" after "grant" each place the term appears in subparagraphs (A) and (B) of paragraph (2).

SEC. 204. ADMINISTRATION.

(a) IDENTIFIABLE ADMINISTRATIVE UNIT.—Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended in the matter preceding paragraph (1) by striking "1990," and inserting "1995,".

(b) STRIKING OF EXPIRED REQUIREMENT REGARDING CERTAIN REPORTS.—Section 375 of the Act (42 U.S.C. 274c) is amended—

(1) in paragraph (3), by striking "receiving funds under section 371"; and

(2) in paragraph (4), to read as follows:

"(4) provide information—

"(i) to patients, their families, and their physicians about transplantation; and

"(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.".

SEC. 205. REPORT.

Section 376 of the Public Health Service Act (42 U.S.C. 274d) is amended—

(1) in the first sentence, by striking "The Secretary" and all that follows through "report on" and inserting "The Secretary shall prepare a report each fiscal year on"; and

(2) by adding at the end the following new sentence: "The biennial report shall be submitted to the Secretary each fiscal year for inclusion in the biennial report required by section 403.".

SEC. 206. STUDY BY GENERAL ACCOUNTING OFFICE.

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by adding at the end the following new section:

"SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.

"(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining—

"(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

"(2) the problems encountered in the procurement and allocation; and

"(3) the effect of State required-request laws.

"(b) REPORT.—Not later than January 7, 1992, and January 7, 1994, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.".

SEC. 207. EFFECTIVE DATE.

Except as otherwise provided in this title, the amendments made by this title shall become effective on October 1, 1990, or on the date of the enactment of this Act, whichever occurs later.

TITLE III—IMMUNOSUPPRESSIVE DRUG THERAPY

SEC. 301. BLOCK GRANTS.

Section 1932 of the Public Health Service Act (42 U.S.C. 300y–22) is amended by striking "1988 through 1990" and inserting "1991 through 1995".

TITLE IV—SEVERABILITY

SEC. 401. SEVERABILITY.

If any provision of this Act, amendment made by this Act, or application of the provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions or amendments to any person or circumstance shall not be affected.

I. SUMMARY OF THE BILL

S. 2946 extends for three years, the program of the National Bone Marrow Donor Registry, a registry of volunteer donors administered by the Department of Health and Human Services. The program is authorized for $17 million in fiscal year 1991 and such funding as may be necessary in fiscal years 1992 and 1993. The legislation includes requirements for the National Registry as well as entities participating in the national system.

S. 2946 also extends for five years the authorization of appropriations for expiring programs of the Organ Transplant Program. These programs are operated by the Division of Organ Transplantation in the Health Resources and Services Administration within the Department of Health and Human Services. The Division is responsible for supporting a program of special project grants to increase organ donation and strengthen or consolidate existing organ procurement organizations (OPOs). The Division also maintains a scientific registry of organ transplant recipients and administers

the Organ Procurement and Transplantation Network (OPTN). In addition, the Division is responsible for providing technical assistance to OPOs and assisting patients, families, and their physicians with information about transplantation. S. 2946 authorizes $5 million for these programs for each of fiscal years 1991–1995.

S. 2946 directs the General Accounting Office to conduct studies on the organ transplant system and the bone marrow transplant system.

S. 2946 extends the authority of the Immunosuppressive Drug Therapy Block Grant Program through 1995.

II. Background and Need

For people suffering from leukemia, aplastic anemia, and related diseases, a bone marrow transplant can mean the difference between life and death. In contrast to matching blood types, finding a suitable donor for a bone marrow donor is much more difficult. The first place to look is in the patient's own family, where matches are found 20 percent of the time. If no suitable donor is found, the only hope is to find a compatible donor is from the public at large.

An OTA report released in 1987 indicated that the preliminary data on unrelated transplants was promising and that greater success could be achieved with improvements in the waiting period for transplants, and with other improvements in the procedures growing out of continuing research. According to the report, the ability of transplant centers to perform transplants with unrelated donors had been seriously hampered by their difficulty in identifying suitable donors. The report suggested that a registry of volunteer potential donors would facilitate a greater number of unrelated bone marrow transplants.

The transplantation of organs in humans, especially the kidney, the heart, and the liver has, since its beginning in the 1950's, become an accepted and effective means of treating a significant number of patients with life-threatening organ failure. However, a serious problem that affects organ transplantation is the wide gap between the need for organs and the supply of donors. At any one time, there are an estimated 20,000 persons waiting for a donor organ to become available, and these numbers continue to grow.

The greatest barrier to increasing the supply of donor organs continues to be the failure of hospitals to provide appropriate counseling to the families of potential donors. This situation continues to exist despite provisions in Federal law. Because the demand for transplantable organs is expected to continue to be considerably greater than the supply, a fair and equitable organ sharing system is critical to the future of a national transplant program that the public will support.

Another serious problem in transplantation is rejection of the donated program by the immune system of the recipient. Immunosuppressive drugs have helped organ recipients to achieve immunocompatibility, but the costs of this drug therapy have put its benefits out of the reach of many organ recipients.

THE NATIONAL ORGAN TRANSPLANT ACT OF 1984

The 98th Congress responded to widespread public interest and involvement in and concern about the field of organ and bone marrow transplantation, particularly the shortage of donors and the cost of transplant procedures, by enactment of the National Organ Transplant Act of 1984 (P.L. 98–507). In addition to prohibiting the buying and selling of organs, the act provided for the establishment of grants to organ procurement organizations and a national organ-sharing system to be overseen by the OPTN. The 1984 Act also established a 25-member Task Force on Organ Transplantation. The legislation also required the Secretary to study the feasibility of establishing a national registry of voluntary bone marrow donors and included the authority to establish such a registry.

THE OMNIBUS RECONCILIATION ACT OF 1986

Building on the foundation for a national transplant policy established by the National Organ Transplant Act, and acting on a number of the recommendations contained in the Task Force's two reports, Congress added section 1138 to the Social Security Act, "Hospitals Protocols for Organ Procurement and Standards for Organ Procurement Organizations." This section provided strong, new enforcement tools to the OPTN. The bill required that all OPOs be Federally certified. It also required all hospitals, as a condition of participation in the Medicare and Medicaid program, to notify the OPO designated in their area about all potential organ donors and to make the families of such donors aware of the option of organ donation. The law also extended Medicare transplant coverage to include outpatient immunosuppressive drugs.

THE HEALTH OMNIBUS PROGRAMS EXTENSION ACT

Included in the Health Omnibus Program Extension Act were provisions concerning the organ transplant program. This legislation reauthorized the grant program for OPOs and encouraged special projects designed to increase the number of organ donors. The Act also clarified Congressional intent that OPOs have a defined service area that is of sufficient size to assure maximum effectiveness and efficiency. The Act took additional steps to assure that organs are shared equitably among transplant patients, and that OPOs assist hospitals in establishing and implementing routine referral and inquiry protocols about organ donation and potential organ donors. It also included provisions, in light of the addition of section 1138 to the Social Security Act, designed to assure that the OPTN is responsive to the interests and concerns of parties affected by its policies and operation and that the Secretary establish procedures for receiving and considering comments critical of the OPTN and work with the OPTN to resolve and problems raised that the Secretary concludes have merit.

The legislation also required the establishment in the Department of Health and Human Services of a national registry of voluntary bone marrow donors and a block grant program that allows states to allocate funds to transplant centers for the purchase of immunosuppressive drugs. The Act clarified that the ban on the

buying and selling of organs included fetal organs, and it required OPOs to screen for the etiologic agent for acquired immune deficiency syndrome.

III. Hearings

The Committee held one hearing on the reauthorization of the National Bone Marrow Registry on Wednesday, March 29, 1990. Testimony was received from three Members of Congress, three witnesses representing family members in search of a suitable unrelated bone marrow donor and witnesses representing the National Heart, Lung, and Blood Institute, the National Marrow Donor Program, and the American Bone Marrow Donor Registry. Additional materials were submitted from other individuals searching for an unrelated marrow donor.

PANEL I

Senator Albert Gore (D–TN).
Representative Vic Fazio (D–CA).
Representative Bill Young (R–FL).

PANEL III

Ms. Sandy Mortenson, Fairfax, Virginia.
Mr. Alvin Atlas, Bethesda, Maryland.
Ms. Kathy Barrett, Woodbridge, Virginia.

PANEL II

Dr. Claude Lenfant, Director, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland.

Ms. Joan Keller, President, American Bone Marrow Donor Registry, Mandeville, Louisiana.

Dr. Robert Graves, Vice-Chairman, Board of Directors, National Marrow Donor Program, St. Paul, Minnesota.

IV. Committee Action

On August 1, 1990 the Committee met to consider a Committee substitute for S. 2946. The Committee agreed unanimously by voice vote to report S. 2946 as amended to the full Senate.

V. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC, September 19, 1990.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Wasington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for S. 2946, the Transplant Amendments Act of 1990, as ordered reported by the Senate Committee on Labor and Human Resources on August 1, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

ROBERT D. REISCHAUER,
Director.

CONGRESSIONAL BUDGET OFFICE—COST ESTIMATE

1. Bill number: S. 2946.
2. Bill title: Transplant Amendments Act of 1990.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on August 1, 1990.
4. Bill purpose: To amend the Public Health Service Act to revise and extend the program establishing the National Bone Marrow Donor Registry, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
Bone marrow donor registry	17	18	18		
Grants for organ procurement organizations	5	5	5	5	5
Administration	1	1	1	1	1
Grants for immunosuppressive drugs	5	5	5		
Total estimated authorization levels	28	28	29	6	6
Estimated outlays:					
Bone marrow donor registry	7	16	18	10	2
Grants for organ procurement organizations	3	4	5	5	5
Administration	(1)	1	1	1	1
Grants for immunosuppressive drugs	3	4	5	2	1
Total estimated outlays	13	25	29	18	8

Note.—Details in this table may not add to totals because of rounding.

The costs of this bill fall within budget function 550.

Basis of estimate: S. 2946 would authorize the Secretary of Health and Human Services to establish and maintain a national registry of bone marrow donors. The bill provides $17 million in fiscal year 1991, and such sums as may be necessary in fiscal years 1992 and 1993 for the registry. CBO estimated the 1992 and 1993 authorizations by increasing the 1991 level for projected inflation. The bill would also establish a maximum penalty of $50,000 for any person who violated the registry's confidentiality of records. Because CBO has no basis to estimate the number of violations that would occur or the amount violators would be penalized, we cannot estimate the amount of revenue that could be recovered as a result of this provision.

The bill would authorize $5 million in each of fiscal years 1991 to 1995 to establish and operate organ procurement organizations. In addition, the bill would extend the authorization for an administrative unit within the Public Health Service to coordinate organ procurement activities in fiscal years 1991 to 1995. The bill did not specify an authorization level for the administrative unit. Based on the 1990 appropriation for the administration, CBO estimates that

this provision would cost approximately $1 million in each of fiscal years 1991 to 1995.

The bill also would authorize $5 million in each of fiscal years 1991 to 1993 to provide immunosuppressive drug therapy, used to prevent the rejection of transplanted organs and tissues, to eligible patients.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Karen Graham.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VI. Regulatory Impact Statement

This legislation is to result in some minor additional paperwork for the Department of Health and Human Services.

VII. Section-by-Section Analysis

S. 2946—TRANSPLANT AMENDMENTS ACT OF 1990

As reported by the Senate Committee on Labor and Human Resources:

Section 1 of the bill cites the Act as the "Transplant Amendments Act of 1990."

Title I of the bill is the "National Bone Marrow Donor Registry." Section (101(a) establishes a National Bone Marrow Donor Registry by amending Title III of the Public Health Service Act, by redesignating Parts J, K, and L, and establishing a new Part I that creates the National Bone Marrow Donor Registry.

Under the new Part I is established section 379(a), which authorizes the Secretary of HHS to establish and maintain a National Bone Marrow Donor Registry that meets the requirements of this section. The section further designates that the Registry shall be under the general supervision of the Secretary of HHS, and under the direction of a board of directors whose composition must include representatives of donor centers, transplant centers, persons with expertise in social science, and the general public.

Section 379(b) requires that the National Bone Marrow Donor Registry established in subsection (a), must establish a system based on donor selection criteria described in subsection (c)(2) for finding bone marrow donors who are suitably matched to unrelated recipients for bone marrow transplantation. This registry must maintain a system of strict confidentiality of donor records in accordance with (c)(5).

The subsection also specifies that the registry must establish and maintain a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated bone marrow donor. A subsection later in the bill (c)(4)(C) require that this

system shall include providing information at the start of the search process, information concerning: the resources available through the National Bone Marrow Donor Registry; the comparative costs of all charges incurred by patients prior to transplantation and the comparative success rates of individual centers; and all bone marrow donor registries meeting standards of donor confidentiality, patient advocacy, tissue typing, and quality standards.

The bill requires the National Bone Marrow Donor Registry to ensure that the pool of potential donors that forms the registry is ethnically diverse so that an individual in a minority group has a comparable chance of finding a suitable unrelated donor as an individual not in a minority group.

The bill requires the National Bone Marrow Donor Registry to collect, analyze, and publish data concerning bone marrow donation and transplantation and to provide information to physicians, other health care professionals and the public regarding bone marrow transplantation.

The Registry is also required to recruit potential bone marrow donors and to support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be bone marrow donors.

Subsection (c) requires the Secretary to establish and enforce within 180 days after the date of enactment of this part, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries; marrow donor collection centers; and marrow transplant centers; standards for tissue typing, donor informed consent, patient advocacy, and quality standards; donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases; procedures to ensure the proper collection and transportation of the bone marrow; standards for providing information to patients, their families, and their physicians at the start of the search process concerning the resources available through the National Registry and all marrow donor registries meeting the standards described in this subsection.

The Secretary must also establish standards for establishing a system of strict confidentiality of records relating to the identity, address, HLA type, and managing donor center for marrow donors and potential marrow donors.

Under subsection (d), the Secretary must establish and provide information to the public on procedures, which may include the creation of a policy committee to advise of policy matters, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the National Bone Marrow Donor Registry is carrying out the duties established in subsection (b). The Secretary shall consult with the board of directors of the National Bone Marrow Donor Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

Subsections (e), (f), (g), and (h), describe the requirements for entities for applying for, obtaining, and maintaining a contract under this section.

Subsection (i) specifies that any person who violates the requirements established by subsection (c)(5)(A) shall be fined by not more than $50,000 or imprisoned by not more than 2 years, or both.

Subsection (j) authorizes appropriations for the National Bone Marrow Donor Registry at $17 million for fiscal year 1991 and such sums as may be necessary for fiscal years 1992 and 1993.

The bill establishes a new section 379A of the Public Health Service Act, which requires the Comptroller General to conduct a study evaluating; the costs and benefits of the search process for an unrelated bone marrow donor among bone marrow donor registries; the extent to which donor registries protect donor confidentiality; the relationship between the National Bone Marrow Donor Registry established under section 379 of the Public Health Service Act and individual donor centers; the effectiveness and appropriateness of policies and procedures of donor centers, transplant centers, and donor registries; the ability of the donor registries to adopt changes in medical understanding and practice; and the costs associated with tissue typing. The Comptroller shall complete this study and submit to the House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources, a report describing the findings of the study and recommendations for legislative action.

Section 102 of the bill provides that the establishment of a new title within the Public Health Service Act will not effect any existing legal obligations for the National Bone Marrow Donor Registry under its previous statutory authorization.

Title II of S. 2946 is entitled, "Organ Transplants." Section 201(a) amends section 371 of the Public Health Service Act to read: "Organ Procurement Organizations".

Section 201(b) of the bill amends Section 371(a) of the Public Health Service Act to allow the Secretary to make grants to and enter into contracts with qualified organ procurement organizations as described in section 371(b) and other nonprofit private entities for the purpose of carrying out special projects. This subsection strikes section 371(a)(4).

Section 201(c)(1) amends section 371(b)(1)(E) of the Public Health Service Act by eliminating the stipulation that qualified organ procurement organizations must have a service area of sufficient size to procure at least 50 donors each year. Instead, the Secretary must establish performance standards by regulation to assure that an OPO has a defined service area that is of sufficient size to assure maximum effectiveness and efficiency in the procurement and equitable distribution of organs. Such area shall either include an entire standard metropolitan statistical area or not any part of such an area. The Secretary is required to propose these criteria within 180 days of the enactment of this section.

Section 201 (c)(2) makes a conforming amendment to repeal section 402(c)(3) of the Health Omnibus Programs Extension of 1988 (P.L. 100-607) as amended by Public Law 101-274.

Section 201(d) of the bill amends section 371(b) of the Public Health Service Act to require the Secretary to publish, not later than 180 days after the enactment of this section, criteria for determining whether an entity meets the service area requirements as established in section 371(a)(1)(E). Section 201(e) makes a technical

correction to P.L. 100-607 regarding repesentation on the board of a qualified GPO.

Section 201(f) of the Act as added by the bill amends Section 371(c) of the Public Health Service Act by extending the authorization of appropriations from 1991 through 1995.

Section 202(a)(1) of the bill changes amends section 371(b)(1) of the Public Health Service Act regarding the minimum qualifications that must be met by an entity seeking the contract to operate the OPTN by deleting the requirement in current law that such an entity must not be engaged in any activity unrelated to organ procurement, effective with contract entered into on or after December 31, 1990.

Section 202(a)(2) of the bill makes changes in the board of directors or advisory board designed to ensure greater continuity of leadership and public participation in the management of the network.

Section 202(b) of the bill amends Section 372(b)(2)(f) to emphasize that the OPTN has a nationwide service area. The bill further provides that the organs must be distributed equitably among transplant patients.

Section 203 of the bill amends section 374 of the Public Health Service Act by revising certain administrative requirements with respect to the grant and contract programs authorized under this part of the Act.

Section 204(a) of the bill amends Section 375 of the Public Health Service Act by extending the authorization of the administrative unit in the Public Health Service that oversees part H of the Public Health Service Act.

Section 304(b) of the bill amends section 375 of the Public Health Service Act to require the Secretary to make avaialble to patients, their families and their physicians a report on the available resources nationally and in each state and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist patients and their families with the costs associated with organ transplantation.

Section 205 of the bill amends section 376 of the Public Health Service Act to revise the Secretary's annual reporting requirement with respect to the scientific and clinical status of organ transplantation and directs that such a report be submitted every two years beginning February 10, 1991 and thereafter.

Section 206 of the bill amends Part H of the Public Health Service Act by establishing a new section 377 that provides for the Comptroller to conduct a study assessing: the extent to which the procurement and allocation of organs have been equitable, efficient, and effective; the problems encountered in such procurement and allocation; and the effect of State required-request laws. The Comptroller shall report the results of the study not later than January 7, 1992 and January 7, 1994.

Section 207 of the bill provides that the effective date of this bill shall be October 1, 1990, or the date of enactment, whichever occurs later.

Title III of S. 2946 is entitled, "Immunosuppressive Drug Therapy." Section 301 of the bill amends section 1932 of the Public

Health Service Act by extending the authority for the Immunosuppressive Drug Block Grant Program from 1991 through 1993.

Title IV, entitled "Severability," includes a severability clause.

VIII. Committee Views

NATIONAL BONE MARROW REGISTRY

In the National Organ Transplant Act (P.L. 98–507), Congress first authorized the Department of Health and Human Services to establish a national registry of voluntary bone marrow donors. When the Secretary found the timing for establishing such a program to be inappropriate, the Naval Medical Research Institute of the U.S. established a registry, pursuant to a directive from the Senate Appropriations Committee (S. Rep. 98–636). The Office of Naval Research contracted with a consortium of organizations to develop and maintain the registry. The consortium included the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers. Under this contract, a central coordinating center performed computer-based searches for potential donors, using data supplied by the local blood centers about the tissue type of persons who have volunteered to be included in the registry. The coordinating center performed additional functions, including: maintaining of records; conducting research on the determinants of successful transplants and facilitating communication and transfer of bone marrow between blood centers and transplant centers. Included in the design of this system were safeguards for donor confidentiality and informed consent. In addition, the coordinating center developed standards for transplant centers participating in the program to ensure that high quality care was provided and procedures were performed in a manner consistent with accepted medical practice.

The primary purpose of the registry was to support civilian bone marrow transplant programs. The Navy indicated a willingness to maintain responsibility for the registry through fiscal year 1988, but preferred to transfer that responsibility to another agency beginning in fiscal year 1989. The committee believed that the Department of Health and Human Services was the appropriate agency to assume responsibility. The Health Omnibus Programs Extension of 1988 (P.L. 100–607) required the Secretary of HHS to establish a registry of voluntary bone marrow donors, under a contract or grant with an appropriate organization or organizations, no later than October 1, 1988. The bill authorized $1.5 million in FY 89 and $1.6 in FY 1990 for this purpose. In FY 89, $2.5 million and in FY 90, $3.7 million were actually appropriated. An emergency supplemental appropriations bill passed in the Spring of 1990 added $6 million to the appropriated levels for FY 90.

The Secretary placed lead responsibility for the registry with the National Institutes of Health. The Secretary decided to continue the arrangement established under the Navy contract, with the coordinating center, the National Marrow Donor Program located in St. Paul, Minnesota, playing a major role in the day to day operations of the registry.

S. 2946 specifies a number of requirements for the National Bone Marrow Donor Registry. The first requirement is that the registry

must have a system, based on donor selection criteria established by the Secretary, for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation. Under current practices, individuals who donate marrow through the NMDP are allowed to donate only once. After an individual has donated marrow his or her name is taken off the active registry. There are certain identified medical reasons for an individual not to donate marrow close to the time of a previous donation. However, the Committee strongly urges the Secretary to examine this issue of repeat donation and to consider the policy of informing a potential donor of the possible risks associated with marrow donation and then allowing the donor to decide whether he or she would be willing to donate only once or multiple times. The Committee requires the GAO, as part of a large report, to examine this issue of repeat donation.

The bill requires the National Bone Marrow Donor Registry to maintain a system of strict confidentiality of donor records. There are a variety of reasons to maintain the confidentiality of the donor. For example, if a transplant ends in the recipient's death, the family might blame the death on the donor. The NMDP has established policies and standards concerning this issue, making this component one of the strongest aspects of the current NMDP program.

The National Bone Marrow Donor Registry is also required to maintan a system for patient advocacy that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor. The Committee learned through the hearing process that a significant deficiency of the National Registry was the lack of patient advocacy services. The Committee believes that this is an essential component of the activities related to the National Bone Marrow Donor Registry and as such should be given high priority. This bill will require the National Bone Marrow Donor Registry to provide patients and their families at the beginning of the search process, information concerning: the resources available through the National Bone Marrow Donor Registry; the comparative costs of all charges incurred by patients prior to transplantation; and all bone marrow registries meeting standards established by the Secretary, including information regarding how to access these registries.

The cost of typing donors for the Registry is another matter of great concern to the Committee. It is the Committee's goal to reduce the cost of typing individual donors and the portion of that cost that must be paid for by the families of transplant recipients. Under the contract for the National Bone Marrow Donor Registry administered first by the Navy and now by the Department of Health and Human Services, of the total amount of the contract ($3.7 million in FY 89), only a small portion ($400,000) was designated for the typing of potential donors. The initial stage, AB typing, costs $50–$75 and the second stage, or DR typing, costs from $175 to $280. The final test for compatibility, the MLC test, costs approximately $100. With little public funding to cover these charges, the responsibility for bringing new donors into the system has fallen largely on the backs of transplant patients and their families. The Committee believes that it is unacceptable for the

majority of the burden of recruiting potential donors to be placed on individuals facing life-threatening illnesses and their families under enormous emotional strain. There will still be a place in the system for donor drives for individuals patients. However, the Committee has provided adequate funding so that the Registry shall no longer rely as it has in the past on private fundraising drives to cover the cost of typing potential donors. The Committee intends that a portion of the authorized funding will be made available to families conducting donor drives. The Committee has found, however, that donor recruitment linked only to the plight of individual patients can result in many problems. The Committee expects that the large Federal commitment to donor typing will sharply decrease the unit cost of typing donors by allowing the Registry to negotiate a high volume discount with typing labs.

The Committee reauthorizes the program of the National Registry of volunteer bone marrow donors and sets the authorization level at $17 million in fiscal year 1991 and such sums as may be necessary in fiscal years 1992 and 1993. In response to concerns about funding to cover the costs of typing, the Committee intends that not less than $10 million of the authorization level should be used to cover the actual costs of typing potential donors.

The National Bone Marrow Donor Registry currently has just over 200,000 potential donors listed. As recent cases have demonstrated, even with a much larger registry there will still be cases where the patient's type is so rare that a suitable donor can not be found. However, the Committee views that it is important to increase the size of the registry to enable an individual to have as reasonable chance of finding a suitable donor as possible. The Committee expects that this substantial increase in the authorization level would only be necessary during the first year or two in order to build the registry; afterwards, only a portion of this will be required in order to maintain the registry.

In addition to the general donor shortage, the Committee is concerned about the serious underrepresentation of minorities in the current donor pool. Because medical experts now know that the chance of finding a matched donor for a particular patient is greater among donors of the same ethnic background as the patient, the current chance of an African American, Asian American, Hispanic American, or Indian American finding a suitable match is unlikely. The Committee believes that an important priority of the National Bone Marrow Donor Registry must be to increase the numbers of minority donors. This bill requires the National Registry to ensure that the pool of potential donors that forms the registry be ethnically diverse so that an individual in a minority group has a comparable chance of finding a suitable unrelated donor as an individual not in a minority group.

One of the barriers to bone marrow transplantation is the high cost associated with the procedure. In addition, individual transplant centers have various policies concerning the kinds of cases they will take and the kinds of matches they are willing to accept as suitable for transplantation. In certain cases, knowing the comparative costs and policies of transplant centers could mean the difference between hope and despair. The Committee, therefore, believes that information concerning comparative costs and policies

must be made available to patients and their families as they begin their search for an unrelated marrow donor. The Committee bill also requires that information about the success rates of each center be made available to the patient.

This bill also specifies additional responsibilities of the National Bone Marrow Donor Registry: to recruit potential bone marrow donors; to support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be bone marrow donors; to provide information to physicians, other health care professionals, and the public regarding bone marrow transplanation; and to collect analyze, and publish data concerning bone marrow donation and transplantation.

In addition to the National Bone Marrow Donor Registry, a private entity called the American Bone Marrow Donor Registry also maintains a pool of potential marrow donors. The American Registry, which is privately funded, is a combination of individual private registries. The American Registry originated in Louisiana in 1984 when over 400 people were typed in response to an appeal for a local child who was searching for an unrelated donor. Other regional donor registries were established by family members in a similar manner as the one in Louisiana. The incorporation of the American Registry unified the separate independent registries and the new organization developed standards and procedures for operation. The Caitlin Raymond International Registry located in Worcester, Massachusetts is the coordinating center for the American Registry.

It is the Committee's view that patients would ultimately be best served by one bone marrow donor program. The Committee therefore, encourages the consolidation of the existing registries under one program that would provide strong and effective patient advocacy as well as ensure donor confidentiality.

The Committee requires, within 180 days of the enactment of this bill, the Secretary to arrange for the coordination of marrow donor registries and marrow donor centers. In doing so, the Secretary shall assure that any bone marrow donor center or registry participating in the national system contains a method for integrating its donor files, searches, and general procedures with the National Bone Marrow Donor Registry. This effort may involve developing interim requirements (until the provisions of new section 379(c) are in place) to be used to determine which registries may participate in the national system. The Committee expects that the Secretary will develop such requirements as expeditiously as possible.

The Secretary is required to establish criteria for donors, including insuring proper informed consent. These criteria will form the basis for the system of finding suitable donors under the National Bone Marrow Donor Program. These criteria shall be based on established medical criteria to protect both the donor and the recipient. For the donor, such standards are necessary in order to prevent to the greatest extent possible any negative side effects or outcomes from marrow donation.

The Secretary is also required to establish and enforce standards for entities participating in the national program, including indi-

vidual donor centers, donor registries, bone marrow collection centers, and bone marrow transplant centers. These standards shall include standards for donor confidentiality and providing for proper informed consent; patient advocacy; system integration (discussed above); bone marrow collection; and quality standards. The Committee urges the Secretary to issue such requirements and regulations in as timely a manner as is possible. The Committee recognizes that the additional requirements included in this bill will require additional personnel. It is the expectation of the Committee that the Secretary will devote an adequate additional number of FTE's in order to fulfill the obligations included in this legislation.

In order to evaluate the current bone marrow transplantation system, the Comptroller General is required to conduct a study evaluating: the costs and benefits of the search process for an unrelated bone marrow donor among marrow donor registries; the extent to which donor registries protect donor confidentiality; the relationship between the National Bone Marrow Donor Program and individual marrow donor centers; the effectiveness and appropriateness of policies and procedures of marrow donor centers, transplant centers, and donor registries; the ability of the donor reigistries to adopt to changes in medical understanding and practice; and the costs associated with tissue typing. The Comptroller shall complete this study and submit a report describing the findings made by the study and recommendations for legislative reform to the Committee and to the House Committee on Energy and Commerce.

ORGAN TRANSPLANT PROGRAM

The National Organ Transplant Act of 1984 (P.L. 98-507) established authority for a grant program for the planning, establishment, initial operation, and expansion of organ procurement organizations. The Health Omnibus Program Extension Act of 1988 (P.L. 100-607) exteneded the authorization of the grant programs and refocused the grants on consolidation of overlapping OPOs and to improve existing OPOs. The Committee bill further extends the availability of this grant program as may be necessary to improve the effectiveness of organ procurement. This program is extended for five years.

Under current law, grants are authorized for special projects undertaken by OPOs that are designed to increase the number of organ donors. The Committee bill amends this law to allow other nonprofit entities to be awarded grants or contracts for special projects. Authority for this program is also extended for five years.

The Committee bill makes changes in the OPTN board of directors in an effort to improve the continuity of leadership and strengthen public accountability and participation.

The OPTN, in addition to maintaining the single national list of all patients waiting for an organ transplant, is also charged with setting much of national transplant policy. In carrying out section 1138 of the Social Security Act, the OPTN has the authority to make important decisions affecting the transplant community. The OPTN board of directors makes policy decisions on such matters as assuring that the organ sharing system is fair and equitable to pa-

tients, that the organ retrieval system is as strong as it can be, and that appropriate minimum standards have been set for hospitals desiring to start a transplant program.

In studying the existing board and its performance, including studies by the Inspector General, by Abt Associates, Inc. on behalf of HRSA, and an internal review conducted by the OPTN contractor, the Committee believes change is necessary, but is reluctant to force any specific model for changing the structure of the board.

To address a variety of problems, the Committee has spent considerable time in meeting with representatives of the Department and the OPTN, as well as reviewing the various studies of the system mentioned above.

The Committee bill does require changes in the board and expects those changes to result in greater continuity in leadership and increased public accountability. While the Committee bill leaves most of the specific changes up to the OPTN board, it does require that an executive and other committees be formed to assist in this purpose. The Committee suggests that a model the board might consider is one where the incoming president is first elected two years before his or her term and serves as chair of a significant committee, then moves on to chair the executive committee, and finally the board itself.

The Committee encourages the board to have greater representation of members of the transplant community, including transplant coordinators, representatives of organ procurement organizations, and others with expertise in organ procurement. The Committee also expects the board will do more to assure that its composition and officers reflect the diverse composition of the U.S. population. The Committee hopes that greater opportunities will be provided to members of the public and voluntary health organizations to serve in leadership positions on the board.

The Committee has found that the Department had not given this program the attention it deserves. As a result, the three different agencies compete for influence over the transplant policy. The Division of Organ Transplantation in HRSA is the agency designated by the Secretary to be the administrative unit for the coordination of Federal organ transplant policy (section 375 of the Public Health Service Act). It is the intent of this Committee that this agency take the lead in this area while coordinating its efforts wth HCFA and the Office of the Assistant Secretary for Planning and Evaluation. In addition, it is expected that the Secretary will ensure reasonable funding for the Division to carry out its responsibilities.

The Committee is especially troubled that eight months have elapsed since HCFA struck down virtually all of the policies of the OPTN (F.R., Vol. 54, No. 241, p. 51802) requiring that policies first be reviewed and receive formal approval by the Secretary. This action has left a policy vacuum that the Committee finds inexcusable.

The Committee hopes that the Secretary will take a more personal interest in this important program and will be in the forefront of insuring its success. At the very least, the Secretary should resolve the bureaucratic struggles among the agencies of the Department and do everything possible to have the OPTN policies in

place no later than 120 days after the date of enactment of this Act.

This legislation changes the minimum qualifications that must be met by an entity seeking the contract to operate the OPTN by deleting the requirement in current law that such an entity must not be engaged in any activity unrelated to organ procurement. By modifying this requirement, the Committee intends to provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role. It is the Committee's intent that the Secretary have the opportunity to select contractors on the basis of their expertise in carrying out the duties and requirements of the OPTN, whether or not an entity is engaged in other activities. Since the current contract is scheduled to expire on September 30, 1990, this revised qualification language of the Committee bill does not effect the Secretary's decision in awarding a new contract this year.

This change, along with changes the Committee has made in the OPTN board of directors, reflect deep concern on the part of the Committee in the manner in which the OPTN has functioned. It is the Committee's intent that this bill will assist a midcourse correction.

The Committee bill would remove the requirement set forth in current law that the area served by an OPO be sufficiently large (if it is not statewide) that the OPO can reasonably expect to procure organs from at least 50 donors per year.

This provision was designed to promote efficiency and effectiveness in the retrieval of organs. To be effective, OPOs must have sufficient resources to hire a core group of compentent employees. This argues against allowing small OPOs, which might not have the resource base to be effective. In addition, OPOs should be held accountable for a vigorous effort, measure by a clear performance standard. It was for these reasons that this provision of the National Organ Transplant Act of 1984 was amended by section 402(c) of the Health Omnibus Programs Extensions of 1988 (P.L. 100-607), to establish a higher standard than in the original act.

This provision of current law has not yet been implemented. Under the 1988 amendments, it was to take effect in the Spring of 1990. However, a substantial number of OPOs would not have satisfied this requirement and organ retrieval might have been seriously disrupted. Therefore, the effective date was extended until January 1, 1992 by P.L. 101-274. This extension was intended not only to give OPOs more time to come into compliance, but also to give the Committee more time to review the requirement carefully.

The Committee bill would remove a numerical standard for performance or effectiveness from the statute. In its place, the bill would require the Secretary to establish performance standards by regulation.

This change does not represent a major shift in the Committee's views about the approriate size of OPOs, but rather a change in how that view is best implemented. It is still the view of the Committee that there should not be OPOs that retrieve from a narrow field and serve only one transplant center exclusively. It is also the Committee's view that metropolital areas should not be divided. This point is reinforced in the Committee bill. In addition, there is

a preference for statewide OPOs. The Committee urges the Secretary to designate statewide agencies (taking into account the provision holding metropolital areas intact) whenever practicable, unless larger area designations would clearly be more effective.

The Committee expects the Secretary to promulgate standards under this provision that will promote both effectiveness and efficiency among OPOs. This standard should include effectiveness in equitable organ sharing and efficiency in maximizing the number of donors nationally as opposed to any one OPO service area. The Committee notes, in particular, that a standard of retrieving a specified number of organ donors per million population would not, by itself, satisfy these requirements. A small OPO might well be able to meet such a standard, but at an unacceptable high cost per organ. Moreover, since organ retrieval cannot be expected to be uniformly successful throughout the country, some OPOs, under this standard, might be able to serve areas of high yield, leaving other OPOs with the difficult task of trying to succeed in areas of low yield. As in virtually all other areas of health policy in which this Committee is involved, it is important that Federal funds devoted to this activity be expended in a cost-effective manner.

The Committee strongly encourages the Secretary to facilitate the consolidation of OPOs. The Committee believes there is no compelling reason to require extensive administrative review by the Secretary where two existing OPOs wish to consolidate or merge into a single OPO. As long as the Secretary, through a minimal review, believes that the purposes of the transplant and organ procurement program are being met, the Committee believes that such mergers or consolidation should be approved expeditiously by the Secretary without a reapplication by the new consolidated entity for that new consolidated service area.

This legislation requires the Comptroller General to complete a study examining: the extent to which the procurement and allocation of organs have been equitable, efficient, and effective; the problems encountered in such procurement and allocation; and the effect of state required-request laws. This report is to be completed and submitted to Congress no later than January 7, 1992.

IMMUNOSUPPRESSIVE DRUG BLOCK GRANT

The Committee realizes that the cost of immunosuppressive drugs is a serious concern for transplant recipients. It has been estimated that one quarter of those medically eligible for organ transplants have no insurance to pay for immunosuppressive drugs that have made organ transplants possible.

These drugs are extremely costly and beyond the financial means of many Americans. Cyclosporine, the most effective immunosuppressive drug, costs $5,000 the first year for a typical transplant patient. In most cases, if the patient cannot afford the immunosuppressive drugs, the patient is not considered a candidate for a transplant. In other cases, transplants are performed, but the transplant recipient must depend on cheaper, less effective drugs that may increase the chance of rejection by up to 50 percent.

The Immunosuppressive Drug Therapy Block Grant can provide assistance to organ transplant recipients whose immunosuppressive

drugs are not covered by existing private or public programs. States may require recipients to pay for part of the cost of their drugs, while taking into consideration their financial resources.

States may purchase the drugs and make them available to certified transplant centers for distribution, reimburse the centers for drugs provided to eligible patients, or select an alternative course of action approved by the Secretary.

This legislation is intended to fill gaps in current coverage for recipients who currently have no funding sources for immunosuppressive drug therapy. It is not meant to become a substitute source of funding for recipients whose drugs costs are already covered.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Part A—Research and Investigation

* * * * * * *

Part H—Organ Transplants

[ASSISTANCE FOR] ORGAN PROCUREMENT ORGANIZATIONS

Sec. 371. (a)(1) * * *

* * * * * * *

(3) The Secretary [may make grants for special projects] *may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects* designed to increase the number of organ donors.

[(4) In making grants under paragraphs (1) and (2), the Secretary shall—

[(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act,

[(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement organizations, and

[(C) with respect to carrying out paragraph (3), give special consideration to proposals from existing organ procurement organizations.]

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) * * *

* * * * * * *

[(E) has a defined service area which is a geographical area of sufficient size such that (unless the service area comprises an entire State) the organization can reasonably expect to procure organs from not less than 50 donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area.]

(E) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire standard metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

* * * * * * *

(2) Not later than 180 days after the date of the enactment of this paragraph, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

[(2)] *(3)* An organ procurement organization shall—

(A) * * *

* * * * * * *

(c) For grants under subsection (a), there is authorized to be appropriated $5,000,000 for each of the fiscal years [1988 through 1990] *1991 through 1995.*

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. (a) * * *

* * * * * * *

(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

(A) be a private nonprofit entity [which is not engaged in any activity unrelated to organ procurement] *that has an expertise in organ procurement and transplantation*, and

[(B) have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 371), transplant centers, voluntary health associations, and the general public.]

(B) have a board of directors or an advisory board—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 317), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transportation Network shall—

(A) * * *

* * * * * * *

(D) assist organ procurement organizations in the *nationwide* distribution of organs. *equitably among transplant patients.*

* * * * * * *

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the [compatability] *compatibility* of such individuals with organ donors,

* * * * * * *

(I) collect, analyze, and publish data concerning organ donation and transplants, [and]

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation[.], *and*

(K) work actively to increase the supply of donated organs.

* * * * * * *

SCIENTIFIC REGISTRY [AND BONE MARROW REGISTRY]

SEC. 373. [(a)] The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

[(b)(1) Not later than October 1, 1988, the Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

[(2) For the purpose of carrying our paragraph (1), there are authorized to be appropriated $1,500,000 for fiscal year 1989 and $1,600,000 for fiscal year 1990.]

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. 374. (a) [No grant may be made under section 371 or 373 or contract entered into under section 372 or 373] *No grant may be made under this part* unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)[(1) In considering applications for grants under section 371—

[(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area.

[(B) the Secretary shall give special consideration to organizations which met the requirements of section 371(b) before the date of the enactment of this section, and

[(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

[The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.]

[(2)] *(1)* A grant for planning under [section 371] *section 371(a)(1)* may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

[(3)] *(2)* Grants under [paragraphs (2) and (3) of section 371(a)] *section 371(a)(2)* may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant *and contracts* made under section 371 or 373. Payments under such grants *or contract* may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants *and contracts*.

(2)(A) Each recipient of grant *or contract* under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant *or contract*, the total cost of the undertaking in connection with which such grant *or contract* was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant *or contract* under section 371 or 373 that are pertinent to such grant *or contract*.

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ADMINISTRATION

SEC. 375. The Secretary shall, during fiscal years 1985 through [1990] *1995* designate and maintain an identifiable administrative unit in the Public Health Service to—

(3) provide technical assistance to organ procurement organizations [receiving funds under section 371], the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and

[(4) not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report on the status of organ donation and coordination services and include in the report

an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.]

(4) to provide information—

(i) to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

SEC. 376. [The Secretary shall, not later than October 1 of each year, publish a report on] *The Secretary shall prepare a report each fiscal year on"; and* the scientific and clinical status of organ transplantation. The Secertary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report. *The biennial report shall be submitted to the Secretary each fiscal year for inclusion in the biennial report required by section 403.*

SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining—

(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

(2) the problems encountered in the procurement and allocation; and

(3) the effect of State required-request laws.

(b) REPORT.—Not later than January 7, 1992, and January 7, 1994, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of study.

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PART I—NATIONAL BONE MARROW DONOR REGISTRY

SEC. 379. NATIONAL REGISTRY.

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the "Registry") that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors that shall include representatives of donor centers, transplant centers, persons with expertise in the social science, and the general public.

(b) FUNCTIONS.—The Registry shall—

(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients,

their families, and their physcians in the search for an unrelated marrow donor;

(3) ensure that the pool of potential donors that form the Registry is ethnically diverse so that an individual in a minority group has a comparable chance of finding a suitable unrelated donor as an individual not in a minority group;

(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

(5) recruit potential bone marrow donors;

(6) collect, analyze, and publish data concening bone marrow donation and transplantation; and

(7) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

(c) CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual donor centers, donor registers, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards that require the provision of information to patients, their families, and their physicans at the start of the search process concerning—

(A) the resources available through the Registry;

(B) all marrow donor registries meeting the standards described in this paragraph; and

(C) in the case of the Registry—

(i) the comparative costs of all charges incurred by patients prior to transplantation; and

(ii) the success rates of individual marrow transplant centers; and

(5) standards that—

(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing donor center for marrow donors and potential marrow donors; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure.

(d) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the

duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (c).

(e) CONSULTATION.—The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

(f) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in (c)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (c)(5)(B), shall be fined not more than $50,000 or imprisoned not more than 2 years, or both.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $17,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.

SEC. 379A. STUDY BY THE GENERAL ACCOUNTING OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates—

(1) the costs and benefits of the search process for an unrelated bone marrow donor among donor registries;

(2) the extent to which donor registries protect donor confidentiality;

(3) the relationship between the Registry established under this part and individual donor centers;'

(4) the effectiveness and appropriateness of policies and procedures of donor centers, transplant centers, and donor registries, including—

(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

(B) the maintenance and updating of donor files; and

(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

(5) the ability of the donor registries to adopt changes in medical understanding and practice; and

(6) the costs associated with tissue typing.

(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.

[PART I] ***PART J*—BIOMEDICAL ETHICS**

SEC. 381. (a) * * *

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[PART J] *PART K*—INJURY CONTROL

RESEARCH

SEC. 391. (a) * * *

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[PART K] *PART L*—HEALTH CARE SERVICES IN THE HOME

Subpart I—Grants for Demonstration Projects

SEC. 395. ESTABLISHMENT OF PROGRAM.

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SEC. 1932. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of making allotments to States to carry out this part, there are authorized to be appropriated $5,000,000 for each of the fiscal years [1988 through 1990] *1991 through 1995.*

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HEALTH OMNIBUS PROGRAMS EXTENSION OF 1988

(Public Law 100–607)

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SEC. 402. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) * * *

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(2) Section 371(b)(1)(i)(III) is amended by inserting before the comma *at the end* the following: "or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility".

[(3) The amendment made by paragraph (1)(A) shall not apply to an organ procurement organization designated under section 1138(b) of the Social Security Act until 2 years after the initial designation of the organization under such section.]

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